REMARKS

This Amendment is submitted in response to the Official Action dated 8 June 2010. Claims 1, 8, 10 and 14 are amended, claims 6 and 7 are canceled, and claims 17-21 are withdrawn. Claims 1-5 and 8-16 remain pending for consideration in the application.

Claim 16 was objected to for misspelling of "wth" on line 2, which is herein corrected.

Claims 6, 9 & 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner contends that the term "an open-ended chamber that is sealed by insertion between sensor walls of said analyzer," is unclear as to what the specific chamber is, in claims 6 & 9. Applicant respectfully points out that this is the open-air testing channel 25 (see FIG. 7 and [0047]) which remains open-ended until inserted into the analyzer. The phrase "an open-ended chamber" is herein amended to "an open-ended channel" to conform more closely to the specification.

The Examiner contends that "to guarantee disposable is located," is unclear in claim 16. This language is herein corrected.

Claims 1-12, 14, & 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lauks et al. 5,096,669 (hereinafter "Lauks")

The Examiner maintains that Lauks teaches each and every element of all of claims 1-12, 14, & 16. Lauks does indeed teach a disposable device to sample, store and move blood across a sensor array to measure the electrochemical properties of blood while safely containing the sample. However, since Lauks is only measuring electrochemical properties the sensing array 66 is built into the disposable enable the device to take the necessary measurements and yet keep the sample completely sealed inside. Applicant's analyzer measures ultrasonic properties of the blood sample, not electrochemical. In this case it is neither physically nor economically feasible to include an ultrasonic sensor array in each disposable device. As such Applicant's device was

specifically designed to work cooperatively with an external ultrasonic sensor array that is housed in the analyzer. This distinction alters both form and function of Applicant's disposable.

Specifically, in order to get accurate ultrasound readings from a very small blood sample volume, as is the case here, the ultrasound waves must pass directly through the sample without interference from the walls of the sample collection device. Therefore, the device of the present invention uses an open channel through the device, with open-air apertures on both opposing sides, so that the sample blood can be exposed and come in direct contact with opposing ultrasonic transducers/sensors which are housed in the analyzer instrument (not in the fluid sampling device). Applicant's small-volume ultrasonic analyzer is unique (see U.S. patent no. 7,523,649), as is its docking of a disposable holding a very small blood sample volume in an analyzer in such a way as to put the blood sample in direct contact with ultrasonic transducers. The configuration of its disposable is likewise novel in its combined use of capillary collection of a small sample, and pressurized transport into an open channel for direct ultrasonic transmission. Again, the ultrasound waves must pass directly through the blood sample without interference from the walls of the disposable sample collection device. Lauks builds the sensors into the disposable and has no open testing area or channel. Claim 1 is herein amended to distinguish Lauks on the basis of "*said testing region further comprising an open-ended channel passing through said thin elongate body and adapted to be sealed off between sensor walls of said analyzer when inserted therein.*"

Although the Examiner cites Lauks' cavity 18 (figure 3, column 5 lines 39-60) as an open-ended chamber that is sealed by insertion between sensor walls of said analyzer, this is incorrect. Cavity 18 is a sealed cavity, and it is not a testing region but only a pool of reagent that gets mixed into the sealed sample. Again, the electrochemical sensors of Lauk's are inside the disposable, not the analyzer, and so Lauks fails to teach or suggest any *open-ended channel passing through said thin elongate body and adapted to be sealed off between sensor walls of said analyzer when inserted therein.*

Claims 2-5 depend from claim 1 and incorporate the same patentable limitations.

Regarding claim 3, the Examiner credits Lauks with an orifice for coupling a pump in said analyzer to said testing region for introducing said pressure-differential (column 10 lines 5-

20). However, the cited components are a manual detent-type pump built into Lauk's disposable. Lauks does not rely on an external pump and fails to teach or suggest any orifice for coupling a pump *in said analyzer* to said testing region for introducing said pressure-differential.

Claims 6 and 7 are canceled.

Claims 8, 10 and 14 are amended exactly as claim 1 and are similarly distinguished, and so the Examiner's rejection of all of claims 1-5, 7-12, 14 and 16 under 35 USC 102 is respectfully traversed.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks et al. 5,096,669.

The Examiner takes official Notice that it is well known in the art that fluidic actuators may comprise a solenoid for the benefit of controlling fluid flow by converting electrical energy to mechanical energy and concludes that it would have been obvious to provide the device of Lauks et al. with a solenoid actuator to control fluid flow. However, official notice is appropriate only "If the knowledge is of such notorious character that official notice can be taken." In re Malcolm, 129 F.2d 529, 54 USPQ 235 (CCPA 1942). Once taken, if the applicant traverses such an assertion the examiner should cite a reference in support of his or her position. M.P.E.P. Section 2144.03. While solenoid actuators may be known components in and of themselves, Applicant traverses on the ground that there are no known prior attempts to employ a solenoid actuator in a portable analyzer that is operative on a resilient plastic bulb to pump blood into an ultrasonic testing area, all of which are claimed elements of claim 13.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks et al. 5,096,669 in view of Kelley US Patent 5,257,984 (hereinafter "Kelley").

Claim 15 incorporates the limitations of amended claim 14 and is similarly distinguished.

In light of the above amendments and remarks, the claims are believed to avoid all the rejections set forth in the Official Action. Thus, all of claims 1-5 and 8-16 are believed to be in condition for allowance. A Notice to this effect is respectfully requested.

Respectfully submitted,

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